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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/537,704

12/12/2005

Richard James Lewis

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EXAMINER

YOUNG, HUGH PARKER

ART UNIT

PAPER NUMBER

1654

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

02/22/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/537,704

Applicant(s)

LEWIS ET AL.

Examiner

Hugh P. Young

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 04 December 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) 5 and 8-14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 & 6-7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date July 3, 2006.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

Detailed action

This is the first Office action on the merits of application No: 10,537,704. There are fourteen claims pending, seven of which are presently under consideration on their merits, the remainder having been withdrawn.

Restriction election and traversal acknowledged

1. Applicant's election with traverse of Group I, claims 1-7, and the species election of SEQ ID NO: 4, in the reply filed on December 4, 2006 is acknowledged. The traversal is on the ground(s) that the claims have unity of invention under PCT Rule 13.1. This is not found persuasive because it is proper to rely on evaluation of novelty or unobviousness when making a determination of unity of invention, the unity of invention of the instant application's claim set being broken by the prior art cited by the Examiner, Balaji et al. (*J. Biol. Chem.* 275(50):39516-22, 2000) does teach the special technical feature of the instant claims, the structure of the chi-conotoxins. In regards the linking claim 8 recited in Applicant's response on page 4, it is drawn to non-elected inventions II-VII. Claim 5 is withdrawn as being drawn to non-elected species, the elected species being found unpatentable (see below).

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-4 and 6-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over McIntosh et al, who describe and claim conotoxin peptides in US Patent 6,767,896 B1, issued July 27, 2004, filed as application No: 09/580,201 on May 26, 2000.

McIntosh claim a conotoxin peptide in their Claim 1, recited as a Markush group of as many as 14 amino acids, with the C-terminal residue as possibly absent. The recited members of the Markush group of possible amino acid residues include all of those claimed in Lewis et al's instant SEQ ID NO: 4, specifically pGlu-GVCCGYKLCH-Hyp-C. It is obvious to select members of a known Markush group for use in or as specific embodiments or species of the genus described by the Markush group. The selection of the second amino acid through to the penultimate amino acid are further impelled by the fact that they correspond to the natural product, chi-Mrl, A or B, as disclosed in the instant Specification as SEQ ID NOS: 1 and 2, respectively, on page 2, lines 4 and 5. The penultimate residue, the modified 4-hydroxyproline is itself a natural, post-translational modification as disclosed by applicant in lines 7-9, page 2 of the Specification. The use of or substitution with pyro-glutamate at the N-terminal end of a conotoxin sequence is similarly discussed by Jones et al, in US Patent Application Publication 2005/0271589 A1, published Dec. 8, 2005. Jones et al. indicate in paragraph [0014], page 2, that the N-terminal Glutamine can be substituted with pyro-Glutamate, designated (Z) in the one-letter sequence codes. They also claim this use of pyro-Glutamate in their claims 1, 2, 24, 29 and 34 (in the Claims). It is interesting to note that the use of an N-terminal pyro-glutamate appears to provide an obvious advantage

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in that Jones et al. describe conotoxin peptide sequences from more than one species of the genus *Conus* (*C. miles*, *tulipa*, *sulcata*, *purpurascens*, and *geographicus*) to which N-terminal pyro-glutamates are attached or substituted regardless of the differences these conotoxins have in regards the remainder of the peptide sequences. Jones et al. similarly state these common substitutions of conotoxin amino acids in US Patent Application Publications 2004/0176278 and 2003/0170222.

Double patenting rejection

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1-4 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 2, 5, 6, 12, 13, 15-21, 38-41, 43, 45, 47, and 49 of copending Application No. 10/537,088. Although the conflicting claims are not identical, they are not patentably distinct from each other because the

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species of conotoxin peptide claimed in the instant 10/537,704 as the elected peptide species SEQ ID NO: 4 is part of the Markush group comprising the conotoxin peptides claimed in the copending 10/537,088 as SEQ ID NO: 4 (in copending claim 2) and SEQ ID NO: 5 (in copending claims 5 and 6). Claims depending from the copending claims 2, 5 and 6 are directed towards further narrowing the Markush group, rendering the instant SEQ ID NO: 4 of 10/537,704 as a species of an ever smaller genus. The peptide sequence SEQ ID NO: 3 (instant claims 1 and 2), which is the foundation of the instant claim set in 10/537,704 is similarly within the bounds of the SEQ ID NO: 4 of the copending 10/537,088.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Objections to the claims

6. Claims 5, 6 and 7 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Claim 5 is drawn to SEQ ID NOS: 10 and 11, rather than the elected species of SEQ ID NO: 4, and was not considered on its merits in this action, other than to note that it is drawn to a rejected independent claim, claim 1.

Conclusion

7. No claims are allowed.

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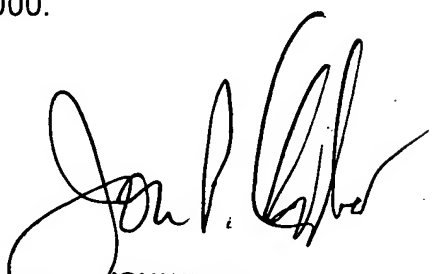
8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hugh P. Young whose telephone number is (571)-272-4988. The examiner can normally be reached on 8:00 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Hugh P. Young Ph.D.

GAU 1654



JON WEBER
SUPERVISORY PATENT EXAMINER